



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/523,237 03/10/00 BECKER

M GP068-03.CN1

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HM22/1106

EXAMINER

SHIBUYA, M

ART UNIT

PAPER NUMBER

1635

DATE MAILED:

11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/523,237

Applicant(s)

BECKER ET AL.

Examiner

MARK SHIBUYA

Art Unit

1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 24, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 442-491 is/are pending in the application.
- 4a) Of the above, claim(s) 442-457, 468-471, and 485-488 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 458-467, 472-484, and 489-491 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Art Unit: 1635

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/01 has been entered.

Election/Restriction

2. Newly submitted claims 442-457, 468-471, and 485-488 are directed to inventions that are independent or distinct from the invention originally claimed (*i.e.*, the invention of newly submitted claims 458-467, 472-484, and 489-491) for the following reasons:

The invention of claims 442-457 and the invention of claims 458-467, 472-484, and 489-491 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the additional limitation of including a promoter sequence in the combination could confer patentability so that the subcombination as claimed is not required for patentability. The subcombination has separate utility such as primer that does not drive promotion.

Art Unit: 1635

The invention of claims 468-471 and 485-488 and the invention of claims 458-467, 472-484, and 489-491 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the additional limitation of including a capture probe in the combination could confer patentability so that the subcombination as claimed is not required for patentability. The subcombination has separate utility such as primer that is not captured by an included capture probe.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 442-457, 468-471, and 485-488 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. This application contains claims 442-457, 468-471, and 485-488 drawn to an invention constructively nonelected by original presentation for prosecution on the merits as set forth in the immediately preceding paragraphs. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Art Unit: 1635

Response to Arguments

4. The applicant's response filed 9/24/01, has been considered. Rejections and/or objections not reiterated from the previous office action mailed 6/19/01, are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Double Patenting

5. Claims 422-441 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 444-465 of copending Application No. 09/565,427. This rejection is maintained for the reasons of record as set forth in the previous Office action.

a. Applicant states that the applicant will address this provisional rejection once claims are indicated to be in condition for allowance. The response filed 9/24/01 at p. 9.

Claim Rejections - 35 U.S.C. § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 458-467, 472-484, and 489-491 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Gemen et al., Patent No. 5,679,553.

a. Claims 458-467, 472-484, and 489-491 are drawn to kits for amplifying a target nucleic acid sequence contained in a target nucleic acid, said kit comprising a first and second amplification oligonucleotide, wherein said first oligonucleotide contains a first base region which

Art Unit: 1635

forms a stable hybrid with a second base region contained in said target nucleic acid under amplification conditions, wherein said second oligonucleotide contains a third base region which forms a stable hybrid with a fourth base region contained in said target nucleic acid, and wherein at least one of said first base region and third base sequences contains one or more ribonucleotides modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety; and that written instructions for use of said kits.

b. Van Gemen et al., Patent No. 5,679,553, at col. 2, lines 42-47, 55-56, col. 4, lines 28-34, 45-61, col. 5, lines 6-11, col. 5, lines 28-67, col. 6, lines 1-15, col. 7, line 19-67, col. 8, line 1-25, col. 10, 49-67, abstract, disclose kits for carrying out methods of amplifying a target nucleic acid sequence contained in a target nucleic acid, said kit comprising a first and second amplification oligonucleotide, wherein said first oligonucleotide contains a first base region which forms a stable hybrid with a second base region contained in said target nucleic acid under amplification conditions, wherein said second oligonucleotide contains a third base region which forms a stable hybrid with a fourth base region contained in said target nucleic acid, and wherein at least one of said first base region and third base sequences contains one or more ribonucleotides modified to include a 2'-O-methyl substitution to the ribofuranosyl moiety; RNA polymerase; and that would inherently have written instructions for use of said kits, as exemplified by the patent itself, which discloses written instructions for use of said kits.

c. Applicant argue that Van Gemen fails to disclose or suggest the use of 2'-O-methyl modified amplification oligonucleotides for amplifying a target nucleic acid sequence.

Art Unit: 1635

d. Applicant's arguments have been carefully considered but are not deemed persuasive. It is noted that the claims are not drawn to methods of "2'-O-methyl modified amplification oligonucleotides for amplifying a target nucleic acid sequence" but to kits that contain oligonucleotides comprising 2'-O-methyl modifications. The specification does not point to any structural requirements for a primer of the claimed invention, that the oligonucleotide of Van Gemen et al. does not fulfill. In other words, there is no difference between the modified oligonucleotide as taught by Van Gemen et al. and an oligonucleotide primer of the claimed invention, other than the use to which the modified oligonucleotide will be put. Any 2'-O-methyl containing oligonucleotide, which is known in the art to be complementary to another sequence, could be packaged in applicant's kit for amplification, with instructions for use, and thereby be encompassed by applicant's claims. Something which is old does not become patentable upon the discovery of a new property. MPEP 2112.

Furthermore, the claim limitations of a kit, which is a product, and instructions for amplification, are not given patentable weight. Being in a kit with instructions is not necessary for using the oligonucleotide primers of the claimed invention and has no significance to the molecular structure of the claimed oligonucleotide. Neither the kit, nor the instruction, are disclosed as limitations to the nucleotide sequence or molecular structure of the modified oligonucleotides. One of ordinary skill in the art would understand, based upon the specification, that the container of the kit, any other unclaimed reagents in the kit, and the instructions for use, could be thrown away, with only the modified oligonucleotides saved for use in a hybridization of

Art Unit: 1635

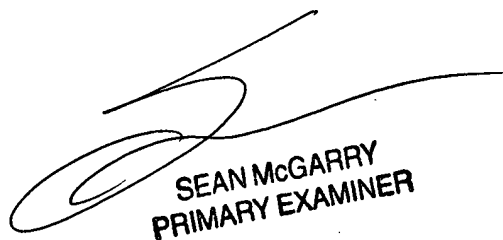
some sort, because the "kit" and the "instructions" are not necessarily or actually employed in a use of the modified oligonucleotides. The "kit" and the "instructions" do not distinguish, imply or change the structure of the claimed primers such that the modified oligonucleotides of Van Gemen et al. could not be used in the claimed invention. Applicant cannot expect to encompass the modified oligonucleotides of Van Gemen et al., or any 2'-O-modified antisense (*i.e.*, complementary) oligonucleotide, simply by claiming them as part of an amplification "kit" with "instructions" for amplification.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC)*, whose telephone number is (703) 308-9355, and/or to the patent analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader* may be reached at (703) 308-0447.

10. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technology Center 1600
November 3, 2001



SEAN MCGARRY
PRIMARY EXAMINER